NDA 20-550/S-010/S-013

GlaxoSmithKline
Attention: Elizabeth Austin, Ph.D.
Project Director, Regulatory Affairs
Five Moore Drive
Research Triangle Park, NC 27709

Dear Dr. Austin:

Please refer to your supplemental new drug applications dated August 9, 1999 (S-10) and October 26, 2000 (S-013), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Valtrex™ (valacyclovir hydrochloride) 500 mg and 1000 mg Caplets.

We acknowledge receipt of your submissions dated:

February 23, 2001
February 26, 2001
March 19, 2001
May 10, 2001 (2)

Your supplemental new drug application (S-010) provides for labeling revisions written to comply with the provisions of the Geriatric labeling requirements promulgated on August 27, 1999 under 21 CFR 201.57(f)(10).

Your "Special Supplement: Changes Being Effected, Labeling" supplemental new drug application (S-013) provides for the addition of coma, decreased consciousness, encephalopathy, psychosis, and visual abnormalities to the **Observed During Clinical Practice** subsection of **ADVERSE REACTIONS**.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text with the following minor editorial revision listed below. Accordingly, these supplemental applications are approved effective on the date of this letter with the following minor revision, as discussed with Dr. Austin on June 19, 2001:

In the VIROLOGY section, under Drug Resistance, the first sentence of the second paragraph will

read:

“Resistance of HSV and VZV to acyclovir occurs by the same mechanisms.”

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert dated May 10, 2001) and must include the revision stated above. This revision is a term of the approval of these applications. Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-550/S-013." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Karen A. Young, RN, BSN, at (301) 827-2335.

Sincerely,

Debra B. Birnkrant, M.D.
Acting Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research